

EXHIBIT B

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**In re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE LITIGATION**

)
) **MDL No. 1456**
) **Master File No. 01- 12257-PBS**
) **Subcategory Case. No. 06-11337**
)

THIS DOCUMENT RELATES TO:

) **Hon. Patti B. Saris**
)

*United States of America ex rel. Ven-A-Care of the
Florida Keys, Inc., et al. v. Dey, Inc., et al.,*
Civil Action No. 05-11084-PBS

) **Magistrate Judge**
) **Marianne B. Bowler**
)
)

**DECLARATION OF NEIL MERKL IN SUPPORT OF DEY DEFENDANTS' REPLY
IN FURTHER SUPPORT OF THEIR MOTION TO EXCLUDE FROM EVIDENCE
THE REPORTS AND TESTIMONY OF THEODORE R. MARMOR, PH. D.**

NEIL MERKL declares, pursuant to 28 U.S.C. § 1746, that:

1. I am a member of the law firm of Kelley Drye & Warren LLP, counsel to Dey Pharma, L.P. (formerly known as Dey, L.P.), Dey, Inc., and Dey L.P., Inc. (collectively "Dey"). I am admitted to practice law in the State of New York and have been admitted *pro hac vice* in this action.

2. I make this Declaration in support of Dey's Reply in Further Support of Dey's Motion *in Limine* to Exclude from Evidence the Reports and Testimony of Theodore R. Marmor.

3. The basis for my knowledge is my review of the files maintained by Kelley Drye & Warren LLP as part of its representation of Dey, including the documents attached hereto, and my own personal knowledge of the facts and circumstances set forth herein.

4. Attached hereto as Exhibit 1 is a true and correct copy of excerpts from the December 18, 2008 deposition of Dr. Robert Berenson.

5. Attached hereto as Exhibit 2 is a true and correct copy of excerpts from the September 12, 2007 deposition of Kathleen Buto.

6. Attached hereto as Exhibit 3 is a true and correct copy of excerpts from the September 13, 2007 deposition of Kathleen Buto.

7. Attached hereto as Exhibit 4 is a true and correct copy of excerpts from the May 15, 2007 and July 17, 2007 depositions of Thomas Scully.

8. Attached hereto as Exhibit 5 is a true and correct copy of excerpts from the May 15, 2007 and July 17, 2007 depositions of Thomas Scully.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on June 30, 2010.

/s/ Neil Merkl

Neil Merkl

EXHIBIT 1

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FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL : MDL NO. 1456
INDUSTRY AVERAGE WHOLESale : CIVIL ACTION
PRICE LITIGATION : 01-CV-12257-PBS
THIS DOCUMENT RELATES TO :
U.S. ex rel. Ven-a-Care of : Judge Patti B. Saris
the Florida Keys, Inc. :
v. :
Abbott Laboratories, Inc., : Chief Magistrate
No. 06-CV-11337-PBS : Judge Marianne B.
- - - - -x Bowler

(CROSS NOTICED CAPTIONS ON FOLLOWING PAGES)

Videotaped deposition of DR. ROBERT BERENSON

Volume I

Washington, D.C.

Wednesday, December 18, 2007

10:10 a.m.

1 Academy Health, which is the organization that
2 represents health services researchers. I had a desk
3 there, but I was basically working as an independent
4 consultant doing health policy projects.

5 Q. Anything related to the reimbursement of
6 Medicare Part B drugs?

7 A. No.

8 Q. Anything related to Medicaid?

9 A. No.

10 Q. And then before that?

11 A. Before that, I worked at HCFA.

12 Q. And in the 2000 to '01 time frame, you
13 were the deputy administrator for HCFA?

14 A. Well, it started in -- somewhere around
15 the summer of 2000, Nancy-Ann DeParle left summer or
16 early fall, I don't remember exactly. Mike Hash
17 became the acting administrator, I became the acting
18 deputy administrator. And then about five weeks
19 before the end, Mike Hash left, and I became -- I
20 didn't change my title, but I became essentially the
21 acting top person.

22 Q. When you say five weeks before the end, is

1 have no direct knowledge of what they did.

2 Q. All right. Did you draft this language
3 that we have been reading?

4 A. I doubt that I wrote it.

5 Q. Okay. Some of the same language shows up
6 in the letter from Administrator DeParle to Congress
7 before, and I was just trying to figure out if you
8 knew who was the drafter of the language.

9 A. It's consistent with my point of view at
10 the time, but I don't remember actually being the
11 person sitting at the typewriter or at the keyboard.

12 Q. Could it have been someone in your staff?

13 A. It could well have been somebody in my
14 staff. This probably would have been produced, both
15 the letter from Miss DeParle and this letter would
16 have been produced by my executive secretariat, which
17 drafts letters. And I'm sure we had something to do
18 with it, with the letter.

19 Q. Last but not least, do you have the book
20 that has 221 in it?

21 A. This one.

22 Q. So showing you what's been marked

1 previously as 221, and ask if you've seen this
2 before?

3 A. I don't think I've seen it before. I'm
4 aware of its existence.

5 Q. This is another program memorandum to the
6 intermediaries and carriers dated November 17th of
7 2000. And it indicates that this program memorandum
8 suspends the PMAB-00-86 dated September 8th, 2000,
9 and then continues, "this is to notify you that you
10 should not use the DOJ data," the DOJ AWP's, I'm
11 paraphrasing now, in your next update of the Medicare
12 payment allowances. Do you remember why -- so let me
13 understand this, and strike all that and I'll back
14 up.

15 So is it your understanding then that the
16 carriers never did actually consider the DOJ AWP's in
17 setting Medicare reimbursement?

18 A. Well, it was to go into effect the
19 following year, so I don't believe it was ever --
20 they may have been doing some preliminary work, but I
21 don't -- I'm pretty sure it was never implemented.

22 Q. And do you know why CMS decided to pull

1 its AWP's in this memo?

2 A. I don't remember the details. I knew that
3 the Congress was getting heavily involved and was
4 preparing -- whether they had prepared or were going
5 to prepare legislation to prevent us from doing this.
6 And they were going to take this issue on themselves.
7 And in the face of that reality, I think we -- we
8 backed off. The Congress basically said, we are
9 going to deal with this issue.

10 Q. Do you know, did anyone from -- well,
11 strike that. Did you have any discussions with
12 Congress as to why they might prevent you from doing
13 this?

14 A. I can't remember that I -- I had any
15 particular -- I don't remember personally having
16 discussions. I know that we were -- there were a lot
17 of congressional letters coming in. I didn't
18 personally, that I can remember, have conversations
19 with -- with staff.

20 Q. Do you recall any reasons Congress
21 expressed as to why they might prevent you from doing
22 this?

1 A. They were hearing the same thing from
2 affected parties that were reflected in these
3 letters, both complaining about access problems and
4 alleged mistakes in how it was being implemented.
5 And Congress is always concerned when they hear about
6 access problems, so it was becoming a very big
7 political issue.

8 Q. Had you had concerns -- any concerns by
9 any pharmaceutical manufacturer with respect to
10 implementing the DOJ AWP's?

11 A. Not -- not that I can remember.

12 Q. Okay. I think that's all I've got. Can
13 we take a short break?

14 THE VIDEOGRAPHER: This is the end of tape
15 three. Off the record at 4:37.

16 (Recess.)

17 THE VIDEOGRAPHER: This is the beginning
18 of tape number four in the deposition of
19 Dr. Berenson. On the record at 2:43.

20 BY MR. MURRAY:

21 Q. Doctor, this is Brian again. You had
22 indicated right before we came back from break that

1 you had remembered the name of that center?

2 A. Yes, the center that had the
3 organizational responsibility for sending out program
4 memoranda was the Center for Beneficiary Services.

5 MS. ALBEE: Excuse me, this is Mrs. Albee.
6 Could the questioner please speak a little louder?

7 MR. MURRAY: Perfect. Sorry. We have
8 actually switched chairs here in D.C. That was my
9 last question. I'm going to pass the witness over to
10 Mr. Neil Merkl, who would like to ask you a few
11 questions. Thank you, Doctor.

12 EXAMINATION BY COUNSEL FOR DEFENDANT DEY

13 BY MR. MERKL:

14 Q. Good afternoon, Doctor. Doctor, my name
15 is Neil Merkl. I represent a company called Dey,
16 D-E-Y. Have you ever had any dealings with Dey?

17 A. No.

18 Q. And you never communicated with Dey in
19 your professional capacity at CMS/HCFA?

20 A. Not that I can remember.

21 Q. When we were talking about Exhibit 221 a
22 minute ago, that was the program memoranda that

1 rescinded the use of the DOJ AWP's. Do you have any
2 recollection at all of how you first learned that you
3 weren't going to be using those or recommending that
4 those AWP's be used any more?

5 MR. LIBMAN: Objection. Mr. Libman.
6 Asked and answered.

7 THE WITNESS: I don't remember any more
8 details about -- I certainly don't remember when I
9 first learned about it. I probably had something to
10 do with participating in a discussion to -- that
11 resulted in the issuance of that memorandum.

12 BY MR. MERKL:

13 Q. So the decision to issue the memorandum
14 was a decision made by CMS as opposed to a directive
15 received from Congress?

16 MR. DRAYCOTT: Objection.

17 THE WITNESS: I believe we did it on our
18 own with -- understanding that Congress would have so
19 directed us if we hadn't done it, but I may be wrong
20 on that.

21 BY MR. MERKL:

22 Q. Who is we?

1 A. We meaning the senior leadership at the
2 time. We are now talking about November, so I would
3 have been in that senior leadership. I don't
4 remember who else would have been involved in such
5 discussions at this time. I don't remember.

6 At that point, I was the acting deputy
7 administrator, and had moved from my position as
8 center director, and don't have a good memory as to
9 specifically what Congress's actions were, but it was
10 -- I do remember that Congress really had felt that
11 our program memorandum was -- was something they
12 wanted to suspend. And I think we anticipated that
13 and withdrew it on our own. But -- so that the
14 Congress indicated their own preference for taking up
15 the issue.

16 Q. You say the Congress felt and the Congress
17 indicated. How was it you became aware of Congress's
18 feelings and indications?

19 A. I don't remember any of the details about
20 it. I'm sure there were -- typically, I don't know
21 in this case, typically there are phone calls and
22 letters that are exchanged between, in some cases,

1 members of Congress and Senators, in other cases
2 staff, with our congressional relations people that
3 are communicated to the senior leadership of the
4 agency.

5 Q. Who are your congressional relations
6 people?

7 A. There is an Office of Legislative Affairs.
8 I don't --

9 Q. For CMS?

10 A. For CMS. Yes. As well as for the
11 department. There are two different offices.

12 Q. Do you know whose job that was at CMS?

13 A. At that time, I don't. It may have been
14 Bonnie Washington in that position at that time, but
15 she may have left by then. I don't know.

16 Q. You say you anticipated Congress might
17 direct CMS not to go ahead?

18 A. I don't remember the details. I know that
19 Congress -- no, I don't know anything. My
20 recollection, which is hazy, is that Congress was
21 preparing legislation to override the program
22 memorandum, but I may not have that exactly right.

1 Q. Did Congress have the ability to direct
2 CMS to do without passing legislation?

3 A. No.

4 MR. LIBMAN: Objection. This is
5 Mr. Libman.

6 BY MR. MERKL:

7 Q. That was a no?

8 A. I don't believe Congress can direct --
9 legislation is how Congress directs the executive
10 branch to act.

11 Q. So unless Congress actually passed
12 legislation, CMS could have gone ahead with the DOJ
13 AWP, had CMS determined to do so?

14 A. I believe that's correct.

15 Q. Okay. Now, you've already told me you
16 don't recall the individuals that participated in a
17 decision not to go ahead. Notwithstanding that you
18 don't know their names, is it possible you remember
19 who it would be by function or title or
20 responsibility?

21 A. We were in the process of -- senior
22 leadership had just changed. Nancy-Ann DeParle had

1 Dr. Berenson. On the record at 4:09.

2 BY MR. MERKL:

3 Q. Doctor, would you take a look at Exhibit
4 446 marked by Abbott's counsel earlier today, please.
5 And if you look at the bottom right-hand corner of
6 the page, in the numbers ending 2762, is a letter
7 from Congress of the United States.

8 A. Okay.

9 Q. And the first letter -- the letter I'm
10 going to talk about in Exhibit 446 is a letter dated
11 September 27th, 2000, with counsel stamp AWP 039-2762
12 through 2763, and it's on the letterhead of Edolphus
13 Towns. Do you see that letter?

14 A. Yes.

15 Q. This is a letter from the Congressional
16 Black Caucus, is that correct?

17 A. I presume, but looking at some of the
18 names -- do they say they are from -- yes. I don't
19 know -- I assume that's right, but I don't really --

20 Q. To Secretary Shalala?

21 A. Yes.

22 Q. Dated September 27, 2000, correct?

1 A. Correct.

2 Q. And it addresses the proposed new AWP
3 that the DOJ was suggesting you use as a basis for
4 reimbursement, correct?

5 A. Correct.

6 Q. Do you recall seeing this letter?

7 A. No.

8 Q. In or about 2000?

9 A. I don't recall seeing it.

10 Q. Earlier you told me when HCFA decided not
11 to go ahead and use the DOJ AWP that it was in
12 response in part to concerns expressed by Congress.
13 Do you recall that?

14 A. That's correct. I did say that.

15 Q. Does this letter reflect the concerns you
16 were telling me about before or is this something
17 else?

18 A. This would be exactly the kind of concerns
19 that Congress would express.

20 Q. Now, when you say you don't recall this
21 letter, do you have any reason to believe one way or
22 the other whether you saw it or did not see it at the

1 time. Is this the type of thing you would have seen?

2 A. No. It went to Donna Shalala, who was not
3 CMS. So if it had gone to our administrator, I
4 probably would have seen it. It might have been
5 routed to somebody at CMS, but this would not be
6 something I would more likely see, because it goes to
7 the department. I mean, it wouldn't be something I
8 would routinely see, because it would be -- that
9 response to it would be handled at the department and
10 it would be less likely that I would be involved in
11 it, although I might have been. I just don't
12 remember.

13 Q. But does this letter accurately reflect
14 concerns that you became -- that you were made aware
15 of that Congress was expressing about the change?

16 MR. DRAYCOTT: Objection.

17 THE WITNESS: This is the kind of concern
18 when I said earlier that politics became a factor,
19 this is the kind of thing I'm referring to. Yes.

20 BY MR. MERKL:

21 Q. Well --

22 A. And I'm not saying politics in a

1 pejorative sense.

2 Q. For instance, if we look at the second
3 paragraph of the letter from Congressman Towns, he
4 says, "this pricing change directed by HCFA will
5 result in a 66 percentage in the respiratory
6 medication Albuterol. This reduction will
7 effectively force the current Medicare providers of
8 home respiratory medication out of business and
9 eliminate this benefit to the African-American
10 community." Is he correct?

11 MR. DRAYCOTT: Objection.

12 MS. ALBEE: Objection.

13 THE WITNESS: I have no idea if he is
14 correct. Just the fact that it's here doesn't make
15 it correct, but it's -- I don't know.

16 BY MR. MERKL:

17 Q. But you have no reason and you had no
18 evidence at the time to suggest he wasn't telling the
19 truth here, right?

20 MR. DRAYCOTT: Objection.

21 THE WITNESS: A lot of this -- I have no
22 reason to think that he is wrong about the 66 percent

1 reduction, that's verifiable, a projection about
2 people going out of business and eliminating care for
3 the African-American community, I don't have any
4 prior assumption whether this is correct or not
5 correct.

6 BY MR. MERKL:

7 Q. Well, isn't it fair to say that this was a
8 concern as expressed by Congress that you would have
9 to take seriously?

10 A. Absolutely.

11 MR. DRAYCOTT: Objection.

12 BY MR. MERKL:

13 Q. And you did take it seriously?

14 A. We did take it seriously.

15 Q. Would you take a look at the next letter,
16 please, starting at page AWP 039-2765. Again, to
17 Secretary Shalala from members of Congress. The
18 first one is Pete Sessions.

19 A. Yes.

20 Q. Do you recognize this letter?

21 A. No.

22 Q. Would you just take a look through it and

1 tell me is this the type of concern that was in fact
2 expressed to you in or about 2000 about the potential
3 use of DOJ AWP's?

4 A. This is the type of concern that was being
5 expressed. Yes.

6 Q. And the substance of what's in here in
7 fact was expressed to you, correct?

8 A. For cancer drugs, yes.

9 Q. And again, you took these concerns
10 seriously, right?

11 MR. DRAYCOTT: Objection.

12 THE WITNESS: Any letter from Congress,
13 you take seriously.

14 BY MR. MERKL:

15 Q. And this letter here, this July 20th
16 letter and the letter that we just looked at from the
17 black -- Congressional Black Caucus were in fact two
18 of the reasons that you elected to continue using the
19 AWP's as published in the Red Book and Blue Book for
20 reimbursement of Medicare rather than going with the
21 DOJ numbers, correct?

22 MR. DRAYCOTT: Objection.

1 THE WITNESS: Yes. That's correct.

2 BY MR. MERKL:

3 Q. Would you take a look at the next letter,
4 please. This is a letter from the Senate dated
5 August 1st, 2000. To Secretary Shalala from John
6 Breaux, Orrin Hatch, Bill Frist, Mary Landrieu and
7 Max Baucus. Take a look. Do you recall this letter?

8 A. No.

9 Q. You don't recall seeing it?

10 A. No.

11 Q. Would you take a look, and tell me if you
12 recall being aware of the sum and substance of the
13 concerns being expressed in this letter?

14 A. I actually hadn't heard a couple of these
15 concerns.

16 Q. Which ones are they?

17 A. The impact on First DataBank's current
18 contract with subscribers, the effect on private
19 insurance contracts. The impact of reloading data on
20 to computers for HCFA. And again, private insurance
21 companies. So those concerns, I wasn't generally
22 aware of.

EXHIBIT 2

Buto, Kathleen

September 12, 2007

Washington, DC

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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL) MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE) CIVIL ACTION
PRICE LITIGATION) 01-CV-12257-PBS
THIS DOCUMENT RELATES TO)
U.S. ex rel. Ven-a-Care of) Judge Patti B.
the Florida Keys, Inc.) Saris
v.) Chief Magistrate
Abbott Laboratories, Inc.,) Judge Marianne B.
No. 06-CV-11337-PBS) Bowler

(captions continue on following pages)

Videotaped deposition of Kathleen Buto

Volume I

Washington, D.C.

Wednesday, September 12, 2007

9:00 a.m.

Buto, Kathleen

September 12, 2007

Washington, DC

Page 59

1 A. Pete Rodler.

2 Q. Rodler.

3 A. I don't remember where he was and
4 whether he was in that office. He may have been.
5 I really don't remember. The name rings a bell,
6 but I can't remember where he was.

7 Q. Do you recall him being someone who was
8 involved with Medicare reimbursement of drugs and
9 Medicaid reimbursement of drugs?

10 A. I don't recall it. The name rings a
11 bell, but I couldn't tell you what issues he
12 worked on.

13 Q. Moving on in your resume you left HCFA
14 -- or -- I'm sorry -- you changed your position
15 at HCFA from associate administrator of policy in
16 July of 1997 and became the deputy director of
17 center for health plans and providers?

18 A. Yes.

19 Q. And tell me about that position.

20 A. Well, first, the reason I changed is we
21 eliminated the associate administrators and
22 reorganized the whole agency. So the

Buto, Kathleen

September 12, 2007

Washington, DC

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1 organization I just described to you kind of went
2 away. What they created in its place were a set
3 of centers. And the center for health plans and
4 providers was intended to bring managed care and
5 fee for service Medicare under the same
6 management.

7 The idea was in part in part to respond
8 to concern that the managed care organization
9 within HCFA was sort of a stepchild, so it wasn't
10 fully staffed, it didn't have the resources, it
11 didn't have the kind of focus it should have.
12 And the idea was to bring those two together.
13 And then as well to bring in from what used to be
14 the bureau of program operations, people who
15 dealt with carriers and fiscal intermediaries,
16 the people who actually wrote the instructions to
17 carriers and intermediaries.

18 So there was an operational arm to this
19 that was really about policy communication to our
20 partners, our contractors, that had always been
21 separate. So the idea was let's create a better
22 pathway and alignment between the regulations

1 that we write and what we tell the contractors to
2 do to implement those regulations. So the whole
3 organization was different.

4 For instance, office of research and
5 demonstrations went to a whole different group
6 called the office of strategic -- something --
7 planning, I think. OSP. I can't remember now.
8 But they reorganized everything.

9 Q. And that was in July of 1997?

10 A. Yes.

11 Q. And was the responsibility for
12 promulgating regulations and implementing those
13 regulations relating to Medicare reimbursement of
14 drugs, was that still within --

15 A. Yes, that organization.

16 Q. Your purview, the center for health
17 plans and providers?

18 A. Now, I should say that the directors of
19 each of these centers were political appointees.
20 So it was a little bit like the associate
21 administrator structure where the political
22 appointees were kind of the key staff to the

EXHIBIT 3

Washington, DC

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1 UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF MASSACHUSETTS

3 - - - - -

4 IN RE: PHARMACEUTICAL) MDL NO. 1456

5 INDUSTRY AVERAGE WHOLESALE) CIVIL ACTION

6 PRICE LITIGATION) 01-CV-12257-PBS

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8 U.S. ex rel. Ven-a-Care of) Judge Patti B.

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10 v.) Chief Magistrate

11 Abbott Laboratories, Inc.,) Judge Marianne B.

12 No. 06-CV-11337-PBS) Bowler

13 - - - - -

14 (captions continue on following pages)

15
16
17 Videotaped deposition of Kathleen Buto

18 Volume II

19
20 Washington, D.C.

21 Thursday, September 13, 2007

22 9:00 a.m.

1 MR. MERKL:

2 (Exhibit Dey 100 was marked for
3 identification.)

4 BY MR. MERKL:

5 Q. Would you please read that?

6 A. (Reading) Yes. I remember the issue
7 in the budget.

8 Q. Do you recognize the article?

9 A. Not really, but I was interviewed a lot
10 when I was at HCFA.

11 Q. When you were interviewed at HCFA did
12 you have to get advance approval from anyone or
13 did people just call you up and you would answer
14 on the phone?

15 A. You would usually advice -- it was
16 actually usually the case the communications
17 office would ask you to be the commenter. So
18 it's -- most news inquiries come through the
19 office of communications.

20 Q. So looking at this article, do you have
21 any reasons to doubt that you gave this interview
22 and made the comments attributed to you in this

1 article?

2 A. I have no reason to doubt.

3 Q. And this article -- am I correct that
4 the time period of the article appears to be the
5 end of 1997?

6 A. This article doesn't have a date on it,
7 does it?

8 Q. That's true. That's true.

9 A. But -- well, let me just say that it
10 could be -- it could also be right after the
11 president's budget -- I mean, there are two time
12 periods when you start to get stories like this.
13 Information about the budget starts to leak out
14 after Thanksgiving. That's usually one time
15 period. And the other is right around the time
16 of the State of the Union message when some of
17 the details start to get out selectively or
18 however, or right after the more detailed
19 summaries of the bills that are being proposed go
20 to Congress.

21 Q. So this would be either Thanksgiving of
22 '97 --

1 A. Well, it's after that. It's more like
2 December, January, February, would be the time
3 period that you would see some of these kinds of
4 reports.

5 Q. So December '97 through early January
6 '98?

7 A. Yeah, probably.

8 Q. And there's a reference here to some
9 prior publicity in September of '96 caused by a
10 Barron's article. I'm reading the third
11 paragraph in. I'll read it for the record and
12 for our friends on the phone.

13 "Last year a series of articles in
14 Barons showed that much of the lush profits made
15 on such outpatient care arose from the high
16 prices paid for drugs and oxygen by Medicaid's
17 parent, the Health Care Financing
18 Administration." And there's a reference to a
19 Barron's article in February '96. "Medicare pays
20 the published price for drugs, known in the trade
21 as average wholesale price, even those firms
22 applying those drugs to patients pay 60 to 90

1 percent below that level."

2 Do you recall that Barron's article and
3 the publicity surrounding it?

4 A. No. But I recall the issue of oxygen
5 and pharmaceuticals being paid too high.

6 Q. Well, do you recall the publicity
7 they're talking about here, where at this point
8 now it's in the press or at least the industry
9 press that that firms are paying 60 to 90 percent
10 below AWP for pharmaceuticals?

11 A. I don't recall the press. But
12 certainly the information was out there.

13 Q. And again, you have no reason to doubt
14 that this article was correctly describing the
15 state of affairs at the time?

16 MR. DRAYCOTT: Objection.

17 A. I have no reason to, you know, question
18 their reference to the Barron's article, if
19 that's what you're talking about, and the
20 situation with oxygen and pharmaceuticals.

21 Q. Now, in the first article they talk
22 about cancer but they talk about home respiratory

1 therapy. That's oxygen and that's also
2 pharmaceuticals as well, because am I correct
3 that Medicare also reimbursed certain
4 pharmaceuticals used in home care for respiratory
5 therapy like albuterol, petroprium, chromium and
6 things like that?

7 A. That's correct.

8 Q. And those drugs were also the subject
9 of this publicity?

10 A. Yes. I think that's correct.

11 Q. Now, you're then quoted to say simply
12 "We need to pay prudently in Medicare for all
13 supplies and services." And again, you're
14 talking about the drugs and the oxygen and the
15 other stuff as well, correct?

16 A. That's correct.

17 Q. And that was of course your goal?

18 A. That was of course my goal.

19 Q. Now, at this time you were anticipating
20 that you would propose to Congress that Congress
21 would switch from just using AWP to a -- if not
22 audited, an actual acquisition cost method of

1 reimbursement, correct?

2 A. Yes. That's what I was anticipating.

3 Q. And you were hoping. And you just
4 explained earlier Congress did not accept that,
5 correct?

6 A. Congress did not accept that.

7 Q. And that was a political decision made
8 by Congress?

9 A. By definition. If Congress did not
10 accept it it was political.

11 Q. But you feel you made your case to
12 Congress for the reasons for switching to an
13 actual acquisition cost, right?

14 MR. DRAYCOTT: Objection.

15 A. I felt we had a good basis for making
16 the proposal. They didn't accept it.

17 Q. And also it was your feeling at the
18 time -- this goes down -- this is kind of a
19 paraphrase -- that had they gone over to an
20 actual acquisition cost system that HCFA could
21 move quickly to in fact implement and conduct an
22 actual acquisition cost system if that was

EXHIBIT 4

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UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL : MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE : CIVIL ACTION
PRICE LITIGATION : 01-CV-12257-PBS

THIS DOCUMENT RELATES TO :
U.S. ex rel. Ven-a-Care of : Judge Patti B. Saris
the Florida Keys, Inc. :

v. :

Abbott Laboratories, Inc., : Chief Magistrate
No. 06-CV-11337-PBS : Judge Marianne B.

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1 then. I guess it was probably -- I can't remember
2 who was in power, but Senator Grassley or Baucus, one
3 of those, which committee.

4 But you know, most of the committee staff
5 and the relevant committees, I had known for years
6 and the members and the ranking members and chairmen.

7 Q. And that would be, that would include the
8 Ways and Means Committee?

9 A. Yes.

10 Q. And the Senate Finance Committee?

11 A. Senate Finance, and Commerce.

12 Q. Commerce.

13 A. Commerce.

14 Q. And these are the folks that you would
15 have had periodic contact with throughout your tenure
16 as president and CEO of FAH?

17 A. Yes. And all through the first Bush
18 Administration, generally people I had known for
19 years. All through the first Bush Administration.

20 Q. And you stayed with FAH until 2001, is
21 that correct?

22 A. Yep.

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1 Q. And then you were appointed --

2 A. Start from scratch, we are in trouble.

3 Q. And then you were appointed to be the
4 administrator of HCFA, is that correct?

5 A. I think I was probably nominated in
6 February-March. I think I was confirmed roughly in
7 May, but I took -- basically became a consultant with
8 HCFA, I think in probably early 2001. Until I was
9 confirmed.

10 Q. All right. So you were nominated, and
11 prior -- I just want to understand that -- prior to
12 being confirmed, you worked as a consultant?

13 A. Prior to being confirmed, I worked as a
14 consultant.

15 Q. So beginning in February or March?

16 A. Yes.

17 Q. And we are talking 2001?

18 A. 2001.

19 Q. And insofar as you know, how is it that
20 you came to be nominated for this position?

21 A. God knows. I think I had a long
22 relationship with first, obviously the first Bush

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1 Administration. And not planning to go back into the
2 government, but I ran into Secretary Thompson or
3 something, and a mutual friend had recommended that
4 he encourage me to do this. So it was largely
5 through Secretary Thompson. And since I had a long
6 history with the Bush Administration, hopefully I was
7 an acceptable choice to the White House.

8 Q. And you stayed there until -- you stayed
9 as administrator of HCFA and CMS, which was one of
10 the first things you did was to change the name,
11 until what, the end of --

12 A. Technically, it was January 4th of 2004,
13 was my technically last day.

14 Q. Will you mark this? This will be 181, I
15 believe. Exhibit Abbott 181.

16 MS. MILLER: Mary Miller on behalf of the
17 Florida Attorney General's office. Florida reserves
18 the right to strike all testimony relating to
19 documents used as exhibits here today with respect to
20 the Mylan case and cross-noticed case, due to failure
21 to produce said documents based on properly served
22 request for production of documents.

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1 try and reform AWP in the late '90s. And a couple of
2 the larger hospital chains obviously also benefited
3 from the spread on outpatient drugs. And they
4 instructed me that it was their interest to not have
5 any reforms happen. So I was a pretty active
6 participant in trying to postpone or delay or kill
7 any reforms of the Clinton Administration. And
8 Nancy-Ann Mindeparro was my predecessor, somebody I
9 knew quite well, spent a lot of time with Congress in
10 there trying to either modify or reduce the reforms
11 that Secretary Shalala and Nancy and others had in
12 mind.

13 And one of the reasons that I became such
14 a rabid advocate for fixing the government was
15 because when I was representing those hospitals, I
16 realized how totally outrageous the policy was. So
17 my history at the Federation probably resulted in me
18 putting on my top one or two or three list of things
19 to fix when I became the HCFA CMS administrator.

20 Q. And do you recall that what the Clinton
21 Administration proposed in approximately 1997 was
22 that Medicare move to actual acquisition cost for the

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1 reimbursement of Medicare Part B drugs?

2 A. Generally, that's -- I remember that.

3 Q. And you worked, you worked against that
4 proposal as part of your duties on behalf of the FH
5 -- FAH, correct?

6 A. Yes.

7 Q. And can you just sort of explain what you
8 mentioned in terms of how it is that hospitals
9 benefit in part from the spread between AWP and
10 actual acquisition costs?

11 A. Probably from the beginning, the biggest
12 issue just because of the volume of the dollars was
13 always Procrit appropriate, and then later Aranesp,
14 and the fact that how, you know, how outpatient
15 departments usually back then for oncology would
16 acquire drugs for, let's say, a two-week dose back
17 then I think was 5 or 600 dollars, they could
18 actually buy it. Medicare was reimbursing 95 percent
19 of average wholesale price, which was frequently 1500
20 dollars or more. And the hospitals obviously had
21 come to rely on that spread just like physicians did.
22 And hospitals, you know, to them, revenue

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1 UNITED STATES DISTRICT COURT

2 FOR THE DISTRICT OF MASSACHUSETTS

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4 IN RE: PHARMACEUTICAL : MDL NO. 1456

5 INDUSTRY AVERAGE WHOLESALE : CIVIL ACTION

6 PRICE LITIGATION : 01-CV-12257-PBS

7 THIS DOCUMENT RELATES TO : U.S. ex rel.

8 Ven-a-Care of The Florida : Judge Patti B. Saris

9 Keys, Inc. :

10 v. :

11 Abbott Laboratories, Inc., : Chief Magistrate

12 No. 06-CV-11337-PBS : Judge Marianne B.

13 - - - - -x Bowler

16 THOMAS A. SCULLY - VOLUME II

17 JULY 13, 2007

18 WASHINGTON, DC

22 (CAPTION CONTINUED)

1 there were these kinds of spread in terms like
2 Ipatropium Bromide and drugs like Albuterol?

3 MR. NEAL: I'll object to the form.

4 A. It's abundantly on the record, for many
5 years, they knew all about it, I'm not sure they
6 understood it that well, but they certainly knew
7 about it.

8 See, when I came in, in 2001, it was
9 very -- I don't think there was a lot of stomach
10 for fixing it, I spent a lot of time trying to
11 create political support for fixing it.

12 Q. So the issue was not knowledge but it
13 was generating the right political support to
14 make these changes; right?

15 A. It's one thing to have the aging
16 committee having a hearing and wave an OIG
17 report, it's another thing to get 218 votes in
18 the House and 60 votes in the Senate to fix it
19 when the constituents -- 218 votes in the House
20 and 60 in the Senate to fix the reimbursement
21 when you have constituents screaming and yelling
22 that they don't want it changed. So it was a

1 political issue.

2 (Exhibit Roxanne 003 marked for
3 identification.)

4 BY MR. GORTNER:

5 Q. I'm going to hand you what's been
6 marked -- pre-marked as Exhibit Roxane 003. For
7 the record, this is an Office of Inspector
8 General report entitled update excessive Medicare
9 reimbursement for Ipatropium Bromide, and it's
10 dated January, 2004.

11 Mr. Scully, I will ask you to quickly
12 flip through this document and let me know if you
13 recognize it?

14 A. I remember, generally, I don't remember
15 reading it, specifically.

16 Q. Would you turn to page one of the
17 report? And at the top of page one there's a
18 paragraph entitled objective, and it reads, to
19 update data provided in a 2002 report comparing
20 Medicaid -- Medicare reimbursement for Ipatropium
21 Bromide to prices available to Medicaid, the
22 supplier community, and the Department of